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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/849,039

05/20/2004

James T. Dalton

P-5235-US14

7024

49443 7590 06/09/2009
Pearl Cohen Zedek Latzer, LLP
1500 Broadway
12th Floor
New York, NY 10036

EXAMINER

KUMAR, SHAIENDRA

ART UNIT

PAPER NUMBER

1621

MAIL DATE

DELIVERY MODE

06/09/2009

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/849,039	Applicant(s) DALTON ET AL.	
	Examiner SHAIENDRA -. KUMAR	Art Unit 1621	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 05 April 2009.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-9, 12-23, 27-34, 36-67, 69-78 and 80-95 is/are pending in the application.
- 4a) Of the above claim(s) 21-23, 32-34, 38-51, 65-67, 76-78 and 82-95 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-9, 12-20, 24-31, 36, 37, 52-64, 68-75, 80 and 81 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 4/5/09 has been entered.

Claims 1-9, 12-23, 27-34, 36-67, 69-78, 80-95 are pending in this application. Claims 10-11, 24-26, 35, 68 and 79 have been canceled.

Claims 21-23, 32-34, 38-51, 65-67, 76-78 and 82-95 have been withdrawn, being drawn to the non elected invention.

Claims 1-9, 12-20, 24-31, 36-37, 52-64, 68-75, and 80-81 are under active consideration.

2. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claim Rejections - 35 USC § 103

3. Claims 1-9, 12-20, 24-31, 36-37, 52-64, 68-75, and 80-81 are rejected under 35 U.S.C. 103(a) as being unpatentable over combined teachings of WO 98/55153 and Tucker et al(US 4,636,505).

Instant claims are directed to a metabolite of a selective androgen receptor modulator compound(SARM), wherein the SARM is represented by the structure of formula I of claim 1 and dependent claims therefrom.

Applicants' arguments were fully consider and were not found convincing. Applicants' arguments are centered and neither WO'153 nor Tucker teaches Q to be acetamido or trifluoroacetamido. The examiner disagrees. While, it is true that Tucker does not teach such substituents, WO'153 expressly teach such substituent. Applicants point out to lines 7-18 of page 7, and the examiner would like to point out to same lines and it is clearly defined that phenyl can be substituted with acylamido, alkylacylamido, and alkylamido.

Applicants' further argue that Tucker does not teach O-bridged SARM wherein phenyl ring is substituted with acetamido. While the examiner agrees with the statement, nonetheless, a combination of reference has been used to render instant claims prima facie obvious and inasmuch as WO'153 teaches such substituten and Tucker teaches equivalence of O and S-bridge, the claimed compounds are rendered obvious.

Applicants' arguments that claims 69-70 are directed to hydroxylated and aminated metabolites and none of the reference are teaching are little if any probative value inasmuch as these metabolites are formed in vivo and it is expected that aminated and hydroxylated derivatives will be formed, absent evidence to the contrary.

Double Patenting

4. Claims 1-9, 12-20, 24-31, 36-37, 52-64, 68-75, and 80-81 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-85 of U.S. Patent No. 6,838,484, or over claims 1-10 of US Patent No. 6,569,896, or over claims 1-5 of US Patent no. 6,492,554. Although the conflicting claims are not identical, they are not patentably distinct from each other because as set forth in the office action of 7/30/07, they are structurally so similar to those claimed herein, and once in-vivo, they are expected to be hydroxylated, or deacylated or hydrolyzed metabolites, absent evidence to the contrary.

5. Claims will be allowed to the extent when Q is acetamido or trifluoroacetamido, Z and Y are nitro and trifluoromethyl respectively, X is O, T is OH and R1 is methyl, and subject to the submission of terminal disclaimer.

6. Any inquiry concerning this communication or earlier communications from the examiner should be directed to SHAILENDRA -. KUMAR whose telephone number is (571)272-0640. The examiner can normally be reached on Mon-Thur 8:00-5:30, Alt Fri.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Daniel Sullivan can be reached on (571)272-0779. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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/SHAIENDRA - KUMAR/
Primary Examiner, Art Unit 1621

S. Kumar
6/5/09